

REMARKS

Review and reconsideration of the Office Action dated May 20, 2005, is respectfully requested in view of the above amendments and the following remarks.

Applicants would like to point out to the Examiner that all the claims remain un-amended. Applicants believe that the present set of claims is novel and not obvious over the Schobel reference.

No new matter has been added by this amendment.

First, Applicants are surprised to see that the Examiner changed her position after indicating in the previous Office Action that the claims were allowable.

Applicants are even more surprised that the Examiner is now requesting proof of the unexpected results.

On page 5 of the Office Action, the Examiner indicated that our previous arguments regarding the novelty of the claims cannot be considered because the arguments must supported by a declaration or affidavit.

The Examiner requested comparative experimentation to prove that the results obtained by the present invention are surprising and limited to the products within the scope of the claims.

Applicants note that all the independent claims require a) solid particles obtained by a fluidized bed spray granulation process, and b) a casing comprising modified cellulose.

Regarding Claims 43 and 45

Applicants note that there are major differences between the cited prior art and the subject matter of Claims 43 and 45. The Examiner failed to consider all the limitations of the claims are required by the US Patent Law.

Applicants respectfully point out to the Examiner that the comparative data requested by the Examiner will not overcome the deficiencies of the prior art regarding Claims 43 and 45 because the final products are different for the reasons set forth below.

Furthermore, in the present case, the Examiner failed to consider the closed transition phrase "**consisting of**" included in the preamble of Claims 43 and 45. The terminology "**consisting of**" is interpreted to mean that any embodiment that does not contain exactly (no more or no less than) the elements recited in the claims is not considered to be encompassed by the claim.

Thus, the scope of these claims is limited to particles encased by coating having **only modified cellulose** (Claim 43) and a method for producing the encapsulated of claim 43 (Claim 45).

Applicants note that the Schobel reference **describes a coating composition** (i.e. casing) **that always has to comprise the three following components:**

- a water insoluble film forming composition (i.e. ethylcellulose),
- an enteric compound (i.e. acrylic polymer)

a plasticizer (i.e. dibutylsebacate)

whereas the ratio of the film former and the enteric compound is between 5:1 and 0,5:1.

The present invention as defined by Claims 43 and 45 does not use any enteric compound or any plasticizer in the coating. In fact, it is the purpose of the present invention as defined in Claim 24 not to include any other materials in the coating apart from the modified celluloses. **The control of the flavor/fragrance release is solely based on the swelling and diffusion characteristics of the modified cellulose (i.e. cellulose that can form thermally reversible gels (see column 4, lines 4-7 of the description) at different temperatures and the reversibility of this effect.**

Additional ingredients such as soluble enteric compound in **amounts mentioned** in the Schobel reference would change the functionality significantly.

Applicants believes that Claims 43 and 45 are novel and not obvious over the prior art.

In present Claims 43 and 45 the feature is based on encasing the particles by coating having **only modified cellulose.**

Thus, in the **hypothetical case** that the particles of the Schobel reference are produce by a fluidized bed spray granulation, the final product will be different from the product of the present invention.

The comparative data requested by the Examiner will not add any value to the subject matter of Claims 43 and 45 because the final products are different.

Finally, Applicants would like to point out to the Examiner that it is not obvious to select the method of the present invention, but once the method is selected, the properties of the produced particles are readily apparent; thus, no demonstration of their properties is required.

Regarding the remaining claims

First, Applicants note that all the independent claims require a) solid particles obtained by a fluidized bed spray granulation process, and b) a casing comprising modified cellulose.

Applicants note that on page 4, lines 8-11, of the Office Action of April 06, 2004, the Examiner **recognized** that the Schobel reference **does not teach** that the aroma and perfume solid particles **are produced by a)**. The Examiner failed to consider all the limitations of the claims as required by the US Patent Law.

In response to the previous Office Actions, Applicants repeated argued that it is essential to produce the solid particles of the present invention by using a fluidized bed spray granulation method, which leads to more spherical granulates than the agglomeration method used by the reference. The more **spherical** the particles, the more uniform the coating will be in terms of thickness. Further, as the occurrence of

edges and peaks of the core particles being coated is eliminated, so too is the occurrence of coating defects. The better the uniformity of the coating, the better the controlled release function of the coating.

In order to substantiate Applicants position, Applicants provided the Examiner (Amendment D) with technical documents that confirm that **the spherical granulate obtained by a fluidized bed spray method is morphologically different from granulates** (SD particles) obtained by the agglomeration method of the Schobel reference. ("Wet granulation process"). See attachments A and B. Please note that attachments A and B were previously submitted along with Amendment D in response to the Office Action of April 6, 2004).

The Examiner failed to consider the attached documents.

Applicants respectfully request the Examiner to take the above-indicated documents to a German translator within the USPTO, to verify the authenticity of the Applicants arguments.

Basically, both documents confirmed that a wet granulation process **does not produce homogeneous granulates**. In the present invention, the solid particles are produced by a process that forms particles that are homogeneous, spherical, and compact. **By their homogeneous build up, the particles can be loaded with a high proportion of active substances, protecting the aroma better from oxidation. By being spherical, the particles are more resistant to friction or rubbing.** The coating can be applied evenly; thus, substantially uniform coating layer

thickness is achievable, and, therewith a defined control release is possible.

In a fluidized bed process (WSG) a spray mixture (solution or suspension) is needed, which is capable of being sprayed **thru nozzles** (see Attachment B, pages 11-12). Thus, a high viscous mixture with significant proportion of cellulose is not suitable for mixtures for a WSG process.

Generally, cellulose in water, depending upon the solubility and type, forms highly viscous solutions/suspensions already in proportion of less than 5%. A 2% mixture of methycellulose or hydroxypropylmethylcellulose and water would, for viscosity reasons, no longer be suitable for WSG process. In Ethanol/water - mixtures, the celluloses are even less soluble and thus more viscous.

The Examiner is further requested to note Fig. 2-12 at page 20 of Reference B, showing morphologies of particles formed in spray drying. Particles may be solid, mushroom-cap, hemispherical, hollow, or burst. The Examiner is also requested to note Fig. 2-14 on page 22 showing particle structures of particles formed by spray drying. These particles are far from providing a core with optimal characteristics.

Applicants would like to point out to the Examiner that it is common knowledge to a person skilled that in particles having a spherical surface will be easier to apply an even homogenous coating (basic chemistry) into the particle. The better the uniformity of the coating, the better the controlled release

function of the coating. This common knowledge and do not required further research.

In the same way, a person skilled in the art will also know that a particle having an un-even surface, occurrence of edges and peaks, will not produce an homogenous coating.

The Schobel reference produces the solid particles in a two-step process comprising a **spray drying** method (column 2, lines 21-30) (first step) and an **agglomeration method** (column 4, 31-46) (second step).

Furthermore, Applicants note that a person of ordinary skill in the art would not have considered using a **fluidized bed spray granulation process** in the Schobel mixture, because the mixture, which contains 90% wet cellulose, **is very viscous and no longer sprayable since the solid proportion of the mixture for the wet granulation is very high.**

A satisfactory control release of the aroma is not possible in the agglomerates according to the Schobel reference because:

- a) due to the heterogeneous nature of the agglomerate, the SD particles exhibit different distances from particle to agglomerate surface, thus different strengths of release properties between the SD-particles exist;

b) in less than spherical agglomerates, the coating layer cannot be applied evenly, thus it is difficult to control the release of substances (aroma and/or perfumes).

Applicants would like to point out to the Examiner that it is not obvious to select the method of the present invention, but once the method is selected, the properties of the produced particles are readily apparent; thus, no demonstration of their properties is required.

Regarding Claims 37 and 44

This claim requires that the modified cellulose is selected from the group consisting of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, ethyl methyl cellulose, or mixture thereof.

Nowhere in the Schobel reference can be found the teaching that the modified cellulose is selected from the group consisting of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, ethyl methyl cellulose, or mixture thereof.

Applicants respectfully point out to the Examiner that the comparative data requested by the Examiner will not overcome the deficiencies of the prior art regarding Claims 37 and 44 because the final products are different for the reasons set forth above.

Accordingly, withdrawal of the rejections is respectfully

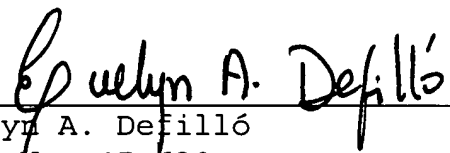
U.S. PATENT APPLICATION No. 09/787,180
AMENDMENT F

ATTY. DOCKET: 3968.019

requested.

Favorable consideration and early indication of allowability is respectfully requested. The Examiner is respectfully requested to contact the undersigned so that a telephonic interview may be arranged.

Respectfully submitted,


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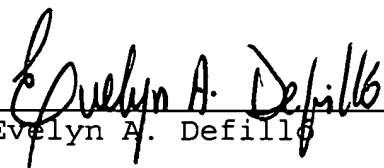
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Date: **September 19, 2005**

CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that a copy of the foregoing AMENDMENT F for U.S. Application No. 09/787,180 filed May 10, 2001, was deposited in first class U.S. mail, with sufficient postage, addressed: **Mail Stop Amendment**, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on **September 19, 2005**.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.


Evelyn A. DeFillio